Senate Study Bill 1021 - Introduced

SENATE/HOUSE FILE _____
BY (PROPOSED BOARD OF PHARMACY BILL)

A BILL FOR

An Act relating to the board of pharmacy, including nonresident pharmacy and outsourcing facility licensure, pharmacist supervision of pharmacy technicians, alternate board members, and enforcement authority.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

S.F. _____ H.F. _____

Section 1. Section 147.107, subsection 2, paragraph a, Code 2015, is amended to read as follows:

a. A pharmacist, physician, dentist, or podiatric physician who dispenses prescription drugs, including but not limited to controlled substances, for human use, may delegate nonjudgmental dispensing functions to staff assistants only when verification of the accuracy and completeness of the dispensing is determined by the pharmacist or practitioner in the pharmacist's or practitioner's physical presence. However, the physical presence requirement does not apply when a pharmacist or practitioner is utilizing an automated dispensing system; ~~or~~ when a pharmacist is utilizing a tech-check-tech program, as defined in section 155A.3; or when a pharmacist is remotely supervising a certified pharmacy technician practicing at a telepharmacy site approved by the board of pharmacy. When using an automated dispensing system the pharmacist or practitioner shall utilize an internal quality control assurance plan that ensures accuracy for dispensing. When using a tech-check-tech program or when remotely supervising a certified pharmacy technician practicing at an approved telepharmacy site, the pharmacist shall utilize an internal quality control assurance plan, in accordance with rules adopted by the board of pharmacy, that ensures accuracy for dispensing. Verification of automated dispensing, ~~and~~ tech-check-tech, and telepharmacy practice accuracy and completeness remains the responsibility of the pharmacist or practitioner and shall be determined in accordance with rules adopted by the board of pharmacy, the board of medicine, the dental board, and the board of podiatry for their respective licensees.

Sec. 2. NEW SECTION. **155A.2A Board of pharmacy —— alternate members.**

Notwithstanding sections 17A.11, 69.16, 69.16A, 147.12, 147.14, and 147.19, the board may have a pool of up to seven alternate members, including members licensed to practice under

this chapter and members not licensed to practice under this chapter, to substitute for board members who are disqualified or become unavailable for any other reason for contested case hearings.

1. The board may recommend, subject to approval by the governor, up to seven people to serve in a pool of alternate members.

2. A person serves in the pool of alternate members at the discretion of the board; however, the length of time an alternate member may serve in the pool shall not exceed nine years. A person who serves as an alternate member may later be appointed to the board and may serve nine years, in accordance with sections 147.12 and 147.19. A former board member may serve in the pool of alternate members.

3. An alternate member licensed under this chapter shall hold an active license and shall have been actively engaged in the practice of pharmacy in the preceding three years, with the two most recent years of practice being in Iowa.

4. When a sufficient number of board members are unavailable to hear a contested case, the board may request alternate members to serve.

5. Notwithstanding section 17A.11, section 147.14, subsection 2, and section 272C.6, subsection 5:

a. An alternate member is deemed a member of the board only for the hearing panel for which the alternate member serves.

b. A hearing panel containing alternate members must include at least five people.

c. The majority of a hearing panel containing alternate members shall be current members of the board.

d. The majority of a hearing panel containing alternate members shall be licensed to practice under this chapter.

e. A decision of a hearing panel containing alternate members is considered a final decision of the board.

6. An alternate member shall not receive compensation in excess of that authorized by law for a board member.

Sec. 3. Section 155A.3, subsections 10 and 11, Code 2015, are amended to read as follows:

10. "*Device*" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory of any of these, ~~that is required under federal or state law to be ordered or prescribed by a practitioner.~~ which is any of the following:

a. Recognized as a device in the official United States pharmacopoeia national formulary or any supplement thereto.

b. Intended for use in the diagnosis of diseases or other conditions, or in the cure, mitigation, treatment, or prevention of diseases or other conditions in a human.

c. Intended to affect the structure or any function of the body of a human, and which does not achieve any of its principal intended purposes through chemical action within or on the body of a human and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

11. "*Dispense*" means to deliver a prescription drug, device, or controlled substance to an ultimate user or research subject by or pursuant to the lawful prescription drug order or medication order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare ~~the~~ a substance for that delivery, or measuring, fitting, adjusting, or otherwise facilitating the use of a medical device or equipment by the patient.

Sec. 4. Section 155A.3, Code 2015, is amended by adding the following new subsections:

NEW SUBSECTION. 17A. "*Equipment*" means any durable or nondurable medical product or article, including but not limited to medical products or articles for personal use.

NEW SUBSECTION. 40A. "*Telepharmacy*" means the practice of pharmacy via telecommunications as provided by the board by rule.

Sec. 5. Section 155A.13A, Code 2015, is amended to read as follows:

155A.13A Nonresident pharmacy license — required, renewal, discipline.

1. *License required.* A pharmacy located outside of this state ~~which~~ that delivers, dispenses, or distributes by any method, prescription drugs or devices to an ultimate user in this state shall obtain a nonresident pharmacy license from the board. The board shall make available an application form for a nonresident pharmacy license and shall require such information it deems necessary to fulfill the purposes of this section. A nonresident pharmacy shall do all of the following in order to obtain a nonresident pharmacy license from the board:

a. Submit a completed application form and an application fee as determined by the board.

b. Submit evidence of possession of a valid pharmacy license, permit, or registration ~~as a pharmacy in compliance with the laws of the state in which it is located, a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located, and evidence of compliance with all legal directions and requests for information issued by the regulatory or licensing agency of the state in which it is located~~ issued by the home state licensing authority.

c. (1) ~~Submit a list of the names, titles, and locations of all principal owners, partners, or officers of the nonresident pharmacy, all pharmacists employed by the nonresident pharmacy who deliver, dispense, or distribute by any method prescription drugs to an ultimate user in this state, and of the pharmacist in charge of the nonresident pharmacy. A nonresident pharmacy shall update the list within thirty days of any addition, deletion, or other change to the list.~~ Submit an inspection report that satisfies all of the following requirements:

(a) Less than two years have passed since the date of

inspection.

(b) The inspection occurred while the pharmacy was in operation. An inspection prior to the initial opening of the pharmacy shall not satisfy this requirement.

(c) The inspection report addresses all aspects of the pharmacy's business that will be utilized in Iowa.

(d) The inspection was performed by or on behalf of the home state licensing authority, if available.

(e) The inspection report is the most recent report available that satisfies the requirements of this paragraph *"c"*.

(2) If the home state licensing authority has not conducted an inspection satisfying the requirements of this paragraph *"c"*, the pharmacy may submit an inspection report from the national association of boards of pharmacy's verified pharmacy program, or the pharmacy may submit an inspection report from another qualified entity if preapproved by the board, if the inspection report satisfies all of the other requirements of this paragraph *"c"*.

(3) The board may recover from a nonresident pharmacy, prior to the issuance of a license or renewal, the costs associated with conducting an inspection by or on behalf of the board for purposes of satisfying the requirement in subparagraph (1), subparagraph division (d). In addition, the nonresident pharmacy shall submit evidence of corrective actions for all deficiencies noted in the inspection report and shall submit evidence of compliance with all legal directives of the home state regulatory or licensing authority.

d. Submit evidence that the nonresident pharmacy ~~maintains records of the controlled substances delivered, dispensed, or distributed to ultimate users in this state~~ has submitted an application to register with the Iowa prescription monitoring program, except as otherwise provided in this paragraph. The prescription monitoring program registration shall be issued if the nonresident pharmacy license application is granted.

If the nonresident pharmacy does not intend to dispense or distribute controlled substances in Iowa, the pharmacy may, in lieu of registering with the prescription monitoring program, submit an application for exemption from reporting to the prescription monitoring program.

e. Submit evidence that the nonresident pharmacy provides~~,~~ ~~during its regular hours of operation for at least six days and for at least forty hours per week,~~ a toll-free telephone service ~~to facilitate communication between ultimate users in this state and~~, the telephone number of which is printed on the label affixed to each prescription dispensed or distributed in Iowa, that allows patients to speak with a pharmacist who has access to ~~the ultimate user's~~ patient records ~~in the nonresident pharmacy, and that the toll-free number is printed on the label affixed to each container of prescription drugs delivered, dispensed, or distributed in this state~~ at least six days per week for a total of at least forty hours.

2. *Pharmacist license requirement.* At least one pharmacist employed by the nonresident pharmacy, who shall be the pharmacist in charge of the nonresident pharmacy, shall maintain a current license to practice pharmacy in Iowa during any period that the nonresident pharmacy is licensed by the board.

~~2.~~ 3. *License renewal.* A nonresident pharmacy shall renew its license on or before January 1 annually. In order to renew a nonresident pharmacy license, a nonresident pharmacy shall submit a ~~renewal~~ completed application and fee as determined by the board, and shall fulfill all of the requirements of subsection 1~~, paragraphs "b" through "e"~~. A nonresident pharmacy shall pay an additional fee for late renewal as determined by the board.

4. *License denial.* The board shall refuse to issue a nonresident pharmacy license for failure to meet the requirements of subsection 1. The board may refuse to issue or renew a license for any grounds under which the board

may impose discipline. License or renewal denials shall be considered contested cases governed by chapter 17A.

~~3.~~ 5. *Discipline.* The board may ~~deny~~ fine, suspend, ~~or~~ revoke, or impose other disciplinary sanctions on a nonresident pharmacy license for any ~~violation of this section, section 155A.15, subsection 2, paragraph "a", "b", "d", "e", "f", "g", "h", or "i", chapter 124, 124A, 124B, 126, or 205, or a rule of the board.~~ of the following:

a. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the United States food and drug administration shall be conclusive evidence of a violation.

b. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the nonresident pharmacy, pharmacist in charge, or individual owner, or if the pharmacy is an association, joint stock company, partnership, or corporation, by any managing officer.

c. Refusing access to the pharmacy or pharmacy records to an agent of the board for the purpose of conducting an inspection or investigation.

d. Any violation of this chapter or chapter 124, 124A, 124B, 126, or 205, or rule of the board.

Sec. 6. NEW SECTION. **155A.13C Outsourcing facility license — renewal, cancellation, denial, discipline.**

1. *License required.* Any compounding facility that is registered as an outsourcing facility, as defined in 21 U.S.C. §353b, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state shall obtain an outsourcing facility license from the board prior to engaging in such distribution. If an outsourcing facility dispenses prescription drugs pursuant to patient-specific prescriptions to patients in Iowa, the outsourcing facility shall obtain and maintain a valid Iowa pharmacy license or Iowa nonresident pharmacy license under this chapter. The board shall make

available an application form for an outsourcing facility license and shall require such information it deems necessary to fulfill the purposes of this section. An outsourcing facility shall do all of the following in order to obtain an outsourcing facility license from the board:

a. Submit a completed application form and application fee as determined by the board.

b. Submit evidence of possession of a valid registration as an outsourcing facility with the United States food and drug administration.

c. If one or more inspections have been conducted by the United States food and drug administration in the five-year period immediately preceding the application, submit a copy of any correspondence from the United States food and drug administration as a result of the inspection, including but not limited to any form 483s, warning letters, or formal responses, and all correspondence from the applicant to the United States food and drug administration related to such inspections, including but not limited to formal responses and corrective action plans. In addition, the applicant shall submit evidence of correction of all deficiencies discovered in such inspections and evidence of compliance with all directives from the United States food and drug administration.

d. Submit evidence that the supervising pharmacist, as described in 21 U.S.C. §353b(a), holds a valid pharmacist license in the state in which the facility is located and that such license is in good standing.

2. *License renewal.* An outsourcing facility shall renew its license on or before January 1 annually. In order to renew an outsourcing facility license, an outsourcing facility shall submit a completed application and fee as determined by the board, and shall fulfill all of the requirements of subsection 1. An outsourcing facility shall pay an additional fee for late renewal as determined by the board.

3. *License cancellation.* If a facility ceases to be

registered as an outsourcing facility with the United States food and drug administration, the facility shall notify the board in writing and shall surrender its Iowa outsourcing facility license to the board within thirty days of such occurrence. Upon receipt, the board shall administratively cancel the outsourcing facility license.

4. *License denial.* The board shall refuse to issue an outsourcing facility license for failure to meet the requirements of subsection 1. The board may refuse to issue or renew a license for any grounds under which the board may impose discipline. License or renewal denials shall be considered contested cases governed by chapter 17A.

5. *Discipline.* The board may fine, suspend, revoke, or impose other disciplinary sanctions on an outsourcing facility license for any of the following:

a. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the United States food and drug administration shall be conclusive evidence of a violation.

b. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the outsourcing facility, supervising pharmacist, or individual owner, or if the outsourcing facility is an association, joint stock company, partnership, or corporation, by any managing officer.

c. Refusing access to the outsourcing facility or facility records to an agent of the board for the purpose of conducting an inspection or investigation.

d. Any violation of this chapter or chapter 124, 124A, 124B, 126, or 205, or rule of the board.

Sec. 7. Section 155A.26, subsections 2, 3, and 4, Code 2015, are amended to read as follows:

2. Make audits of the supply and inventory of controlled substances and prescription drugs in the possession of any and all individuals or institutions authorized to have possession of any controlled substances or prescription drugs<u>, regardless</u>

of the location of the individual or institution.

3. Conduct routine and unannounced inspections of pharmacies, drug wholesalers, and the offices or business locations of all individuals and institutions authorized to have possession of prescription drugs including controlled substances or prescription devices, regardless of the location of the office or business.

4. Conduct inspections and investigations related to the practice of pharmacy and the distribution of prescription drugs and devices in and into this state.

Sec. 8. Section 155A.33, Code 2015, is amended to read as follows:

155A.33 Delegation of technical functions.

A pharmacist may delegate technical dispensing functions to pharmacy technicians, but only if the pharmacist is physically present to verify the accuracy and completeness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative. However, the physical presence requirement does not apply when a pharmacist is utilizing an automated dispensing system or a tech-check-tech program or when a pharmacist is remotely supervising a certified pharmacy technician practicing at a telepharmacy site approved by the board. When using an automated dispensing system or a tech-check-tech program, or when remotely supervising a certified pharmacy technician practicing at an approved telepharmacy site, the pharmacist shall utilize an internal quality control assurance plan that ensures accuracy for dispensing. Verification of automated dispensing, ~~and~~ tech-check-tech, and telepharmacy practice accuracy and completeness remains the responsibility of the pharmacist and shall be determined in accordance with rules adopted by the board.

Sec. 9. NEW SECTION. **155A.45 Inspection reports — disclosure.**

Notwithstanding section 272C.6, subsection 4, paragraph *"a"*,

an inspection report in possession of the board, regardless of whether the report is based on a routine inspection or an inspection prompted by one or more complaints, may be disclosed to the national association of boards of pharmacy's inspection network.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to the operation of, and persons and activities regulated by, the board of pharmacy.

The bill provides for remote pharmacist supervision of a certified pharmacy technician practicing at an approved telepharmacy practice site, pursuant to rules of the board.

The bill permits the board to recommend, subject to approval by the governor, a pool of up to seven qualified individuals to serve as alternate board members to ensure the availability of an unbiased quorum of board members to hear a contested case. The bill identifies the maximum term for an alternate board member, provides that an individual who previously served on the board may serve as an alternate board member, provides for compensation when the alternate member serves on a hearing panel, establishes requirements for the composition of a hearing panel containing alternate board members, and provides that the decision of a hearing panel containing alternate board members is considered a final decision of the board.

The bill amends the definitions of "device" and "dispense" to more closely align with industry standard definitions and to clarify the activities that may be included as a function of dispensing. The bill also defines the terms "equipment" and "telepharmacy" as they relate to the practice of pharmacy.

The bill amends provisions relating to the licensure of nonresident pharmacies that provide prescription pharmaceutical products to patients located in Iowa. The bill requires the pharmacist in charge of a nonresident pharmacy to maintain a license to practice pharmacy in Iowa. The bill clarifies

the information required for license application, including evidence of recent inspection of the pharmacy and defining the elements of an acceptable inspection. The bill describes and identifies various entities that may be employed to perform an inspection acceptable for Iowa licensure. The bill authorizes the board to recoup from a nonresident pharmacy any costs incurred by the board in completing an inspection of the nonresident pharmacy if the nonresident pharmacy cannot provide an acceptable inspection report.

The bill requires that an applicant for a nonresident pharmacy license must include with the application either evidence that the nonresident pharmacy has registered to submit controlled substances prescription records to the Iowa prescription monitoring program (PMP) or has requested exemption from reporting to the PMP based on exemption criteria established by the board pursuant to Code section 124.552. The bill eliminates the requirement that a nonresident pharmacy maintain minimum hours and days of operation, requiring in lieu thereof that a pharmacist with access to patient records be readily available to speak to patients via a toll-free telephone number at least six days per week for a total of at least 40 hours.

The bill authorizes the board to deny an application for a nonresident pharmacy license if the applicant fails to meet the application requirements and authorizes the board to refuse to issue or renew a nonresident pharmacy license for any grounds under which the board may impose discipline.

The bill amends the grounds for disciplining nonresident pharmacies. The board may impose discipline for any violation of the federal Food, Drug, and Cosmetic Act or regulations promulgated under the Act including the issuance by the United States food and drug administration of a warning letter; conviction of a crime related to prescription drugs or the practice of pharmacy by the owner, managing officer, or the pharmacy; refusal to provide the board's agent access to the

pharmacy or pharmacy records for purposes of inspection or investigation; and any violation of Iowa law or rule of the board relating to the practice of pharmacy and the distribution of prescription products in Iowa. For nonresident pharmacies, the bill adds that the board has the option to fine the nonresident pharmacy, in addition to license suspension, revocation, and other sanctions.

The bill adds a new license classification for outsourcing facilities, for the purpose of licensing and regulating any compounding facility that is registered under federal law as an outsourcing facility. The bill establishes the requirements for application and licensure; license renewal, cancellation, and denial; and establishes grounds for discipline of the outsourcing facility license identical to the disciplinary procedure available regarding nonresident pharmacies.

The bill clarifies that the officers, agents, inspectors, and representatives of the board may perform functions and activities relating to authorized enforcement activities regardless of the location of the office or business that is the subject of the enforcement activities. The bill authorizes the board to provide reports of inspections of board licensees to the national association of boards of pharmacy's inspection network, a closed network of information regarding individual states' licensees that compiles information and makes that information available to other state boards of pharmacy for purposes of regulating the subject licensees.